Supreme Court, U.S.
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No. 96-562 (4)

IN THE
Supreme Court of the United States
OCTOBER TERM, 1996

ORGANON INC.,

Petitioner,

v.

DAVID A. KESSLER, M.D.,
Commissioner of Food and Drugs,
BRUCE LEHMAN, Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks, and
GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

REPLY BRIEF FOR PETITIONER

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RULE 29.6 STATEMENT

This Petition is filed on behalf of Organon Inc. The parent company of Organon Inc. is Akzo Nobel. Organon Inc. does not have any nonwholly owned subsidiaries. The other parties to the proceedings in the United States Court of Appeals for the Federal Circuit were: Merck & Co., Inc. and MSD Technology, L.P.; Schering Corporation; Bracco Diagnostics Inc. and Bracco International B.V.; Hoffmann-LaRoche Inc. and Syntex (U.S.A.) Inc.; David A. Kessler, M.D.; Bruce A. Lehman; and the Generic Pharmaceutical Industry Association.

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ORGANON'S REPLY TO THE VARIOUS OPPOSITIONS TO ITS PETITION FOR A WRIT OF *CERTIORARI*

In their Conditional Cross-Petition for a Writ of *Certiorari* (No. 96-761), Cross-Petitioner Generic Pharmaceutical Industry Association ("GPIA") stated that

> Organon Inc. filed a petition [for a writ of *certiorari*] similar to Bracco's in No. 96-562. However, as the Federal Respondents' brief in opposition to that petition pointed out, Organon's patent expired on November 6, 1996, depriving that matter of any live controversy. The Organon petition did not suggest any other fact or circumstance that would prevent its case from having become moot at that time.

GPIA's Cross-Petition at 1 n.1. The other Respondents/Cross-Petitioners in this matter have also complained that Organon "has not suggested any other situation that would present a live controversy." Brief for the Federal Respondents in Opposition at 9 n.7. Petitioner Organon Inc. ("Organon") therefore respectfully files this Reply Brief for the limited purpose of correcting the Respondents/Cross-Petitioner's misstatements that Organon's petition for a writ of *certiorari* is moot.

Under the decision rendered by the United States Court of Appeals for the Federal Circuit (the "Federal

Circuit") in this matter, the expiration date for United States Patent No. 3,927,046 ("the '046 patent") licensed by Organon became November 19, 1995. However, according to the reading of the relevant statutory scheme advanced by Organon throughout this litigation, as well as the decision by the United States District Court for the Eastern District of Virginia (the "district court"), the expiration date for the '046 patent should have been November 6, 1996.

Because November 6, 1996 has already passed, Respondents have simplistically concluded that Organon's petition is moot. What Respondents overlook, however, is that significant legal rights may be affected by a determination of the *proper* patent expiration date for the '046 patent, even if the latest possible patent expiration date has already passed. For example, there currently is a license agreement with an unaffiliated third party, under which that third party has certain obligations depending upon, *inter alia*, the expiration date of the 046 patent. Consequently, a determination of the proper patent expiration date for the '046 patent could affect Organon's legal rights *vis-a-vis* this third party.

This Court has recognized that "[w]hen collateral effects of a dispute remain and continue to affect the relationship of litigants, the case is not moot." *Firefighters Local Union No. 1784 v. Stotts*, 467 U.S. 561, 585-86 (1984) (O'Connor, J., concurring) (footnote omitted) (*citing Franks v. Bowman Transp. Co.*, 424 U.S. 747, 755-57 (1976); *Super Tire Eng'g Co. v. McCorkle*, 416 U.S. 115, 121-25 (1974); *Gray v. Sanders*, 372 U.S. 368, 375-

76 (1963)). The Respondent in *Firefighters* argued to this Court that the appeal in that case was moot because the employees who had been laid off "were restored to duty only one month after their layoff, and that those who were demoted have now been offered back their old positions." *Firefighters Local Union No. 1784*, 467 U.S. at 568-69. This Court noted, however, that the employees who had been returned to their proper positions were also affected by the loss of seniority, and that the employees had possible claims for backpay. *Id.* at 571. Because this Court also realized that the determination of the lawfulness of the layoff in the pending appeal would also be conclusive in any future claims for backpay, this Court held that the Petitioners still had a concrete interest in the outcome of the appeal sufficient to "foreclose any claim of mootness," *id.* at 572, and proceeded to review the merits of the case.

Similarly, in *Southern Pacific Co. v. ICC*, 219 U.S. 433 (1911), this Court also recognized that the potentially preclusive effect that a judgment might have on future litigation mandates against a finding of mootness. In *Southern Pacific*, this Court addressed an administrative order that had expired pending appeal to this Court. *Id.* at 452. This Court rejected Respondents' mootness argument, however, because the Petitioner railroad companies faced possible liability for reparation claims if the Commission's expired order that the railroads had charged excessive rates was allowed to stand unreviewed by the Court. *Id.*

Consequently, this Court held that the appeal was not moot, and reviewed the merits of the Petitioners' appeal.[1/]

In this case, Organon faces the same dilemma faced by the Respondents in *Firefighters* and *Southern Pacific*. If Organon does not pursue its appeal in this case to this Court, Organon might be collaterally estopped from relitigating the proper expiration date for the '046 patent in any subsequent litigation with third parties. Under this Court's holdings in *Firefighters* and *Southern Pacific*, therefore, Organon still has a very real and concrete interest in litigating the *proper* expiration date for the '046 patent,

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1/ The principle that cases are not moot where they carry with them attendant legal consequences and liabilities has also been clearly established by this Court in the criminal context. This Court has held on numerous occasions that a case which has arguably been rendered moot by the defendant serving his entire sentence while his appeal is pending is *not* moot unless "there is no possibility that any collateral legal consequences will be imposed on the basis of the challenged conviction." *Sibron v. New York*, 392 U.S. 40, 57 (1968). This Court has therefore held that collateral legal consequences such as being subject to deportation or denial of American citizenship, loss of the right to run a licensed business, and being subject to longer sentences under recidivist statutes are sufficient to save a criminal case from mootness. *See generally Sibron*, 392 U.S. at 54-56; *Fiswick v. United States*, 329 U.S. 211, 220-23 (1946); *Ginsberg v. New York*, 390 U.S. 629, 633 n.2 (1968); *United States v. Morgan*, 346 U.S. 502, 512-13 (1954).

even if that date has already passed. *See, e.g., Sibron v. New York*, 392 U.S. 40, 56-57 (1968) ("It is always preferable to litigate a matter when it is directly and principally in dispute, rather than in a proceeding where it is collateral to the central controversy."). Organon therefore retains the legal right to seek, through this appeal, the same declaratory judgment that it originally sought in the district court, setting the proper expiration date for the '046 patent. *Super Tire Eng'g Co.*, 416 U.S. at 121-22. Organon's petition for a writ of *certiorari* is not moot.

CONCLUSION

For all of the foregoing reasons, Petitioner Organon Inc. respectfully submits to this Court that its petition for a writ of *certiorari* is not moot and should be granted to address the important questions of federal law and policy outline by Organon in its petition.

Respectfully submitted,

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